

### **REMARKS**

This responds to the Office Action dated on August 15, 2007. Claims 1, 7, 11, 18, 19, 32, 35, and 43 are amended. No claims are added. Claims 10 and 33 are canceled. As a result, claims 1-9, 11-32, and 34-48 are now pending in this patent application.

Applicant respectfully submits that the amendments to the claims are fully supported by the specification and no new matter has been added. Applicant hereby respectfully requests further examination and reconsideration of the application in view of the following remarks.

#### **Telephone Interview**

Applicant thanks Examiner Flory and Primary Examiner Manuel for the courtesies extended in conducting a telephone interview with Applicant's representatives, Suneel Arora and Michael P. Horvath, on November 27, 2007. During the telephone interview, Applicant's representatives discussed proposed amendments to the claims with respect to the rejections of record. Such proposed amendments have now been included in the listing of claims herein. The Examiner indicated that the proposed amendments to the claims would seem to overcome the rejections and art of record. However, the Examiner reserved the possibility of performing a further search.

#### **§102 Rejection of the Claims**

1. Claims 1-6, 16, and 17 were rejected under 35 U.S.C. § 102(b) for anticipation by Siegel (U.S. Patent No. 5,062,841). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Applicant cannot find each and every recitation in claims 1-6, 16, and 17 in Siegel. For instance, Applicant cannot find in Siegel "a physiological sensor that includes at least one biocompatible body, the body sized and shaped to be implanted within a myocardium of a subject", as recited in amended claim 1.

Instead, Siegel apparently relates to an "implantable pump for the delivery of insulin". (Siegel at Abstract.) Siegel states that the pump includes a "cylindrical housing 5 cm in length with a circular internal base area of 2 cm<sup>2</sup> . . . [made] from a suitable rigid material such as polymethylmethacrylate." (Siegel at col. 12, lines 65-67.) Applicant respectfully submits that

Siegel does not appear to show a “body sized and shaped to be implanted within a myocardium of a subject”, as presently recited in claim 1. For at least this reason, Applicant respectfully submits that Siegel does not show each and every recitation of claim 1.

Additionally, dependent claims 2-6, 16, and 17 depend from independent claim 1. Accordingly, these claims incorporate the features of claim 1. For reasons analogous to those stated above with respect to claim 1, claims 2-6, 16, and 17 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-6, 16, and 17 are allowable over Siegel and respectfully requests reconsideration and withdrawal of this rejection.

2. Claims 1-7, 10-17, 19-29, 37, 43, and 46 were rejected under 35 U.S.C. § 102(e) for anticipation by Lew et al. (U.S. Patent Publication 2003/0100822, hereinafter Lew ‘822). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

As an initial note, Applicant has canceled claim 10, thereby rendering the rejection of claim 10 moot.

Applicant cannot find each and every recitation in claims 1-7, 11-17, 19-29, 37, 43, and 46 in Lew ‘822. For instance, Applicant cannot find in Lew ‘822:

- “an implantable transducer; and a physiological sensor that includes at least one biocompatible body, . . . wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer to provide an indication of the physiological condition”, as recited in amended claim 1;
- “transmitting acoustic energy to the body and the myocardium, the acoustic energy transmitted using an implantable transducer”, as recited in amended claim 19; or
- “an implantable medical device, including one or more acoustic transducers configured to provide acoustic energy to the one or more bodies and to receive responsive acoustic energy, the implantable medical device configured to detect

and provide an indication of a change in the physiological condition by using the responsive acoustic energy to detect the change in the physical property of the one or more bodies”, as recited in amended claim 43.

Instead, Lew ‘822 apparently relates to an “implantable chip biosensor for detecting an analyte in vivo in body fluids”. (Lew ‘822 at Abstract.) Lew ‘822 states that “[t]he ultrasound scanner 15, FIG. 1, is designed to measure the glucose concentration based on the length displacement of the glucose-sensitive filament in the biosensor chip 10 implanted under the subcutaneous layer of human skin.” (Lew ‘822 at page 7, paragraph [0090]; and Fig. 1.) Lew ‘822 further states that “[t]he ultrasound transducer 15 located outside of the body scans the biosensor chip 10 and captures the image of the hydrogel filament 11.” (Lew ‘822 at page 7, paragraph [0091]; and Fig. 1.) Applicant respectfully submits that the transducer of Lew ‘822 does not appear to be an implantable transducer or an implantable medical device, as recited in claims 1, 19, and 43. For at least this reason, Applicant respectfully submits that Lew ‘822 does not show each and every recitation of claims 1, 19, and 43.

Additionally, dependent claims 2-7, 11-17, and 37 depend from independent claim 1; dependent claims 20-29 depend from independent claim 19; and dependent claim 46 depends from independent claim 43. Accordingly, these claims incorporate the features of one of claims 1, 19, and 43. For reasons analogous to those stated above with respect to claims 1, 19, and 43, claims 2-7, 11-17, 20-29, 37, and 46 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-7, 11-17, 19-29, 37, 43, and 46 are allowable over Lew ‘822 and respectfully requests reconsideration and withdrawal of this rejection.

3. Claims 1-33, 36-38, and 40-46 were rejected under 35 U.S.C. § 102(e) for anticipation by Slepian (U.S. Patent Publication 2002/0176849, hereinafter Slepian ‘849). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

It is initially noted that Applicant has canceled claims 10 and 33, thereby rendering the rejection of claims 10 and 33 moot.

Applicant cannot find each and every recitation in claims 1-9, 11-32, 36-38, and 40-46 in Slepian '849. For instance, Applicant cannot find in Slepian '849:

- “an implantable transducer; and a physiological sensor that includes at least one biocompatible body, . . . wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer to provide an indication of the physiological condition”, as recited in amended claim 1;
- “an implantable acoustic transmitter, to provide energy to the spheres and the myocardium; and an acoustic receiver, to receive energy from at least one of the spheres and the myocardium, wherein the change in the at least one physical property is chronically detectable using the energy to provide an indication of the physiological condition”, as recited in amended claim 18;
- “transmitting acoustic energy to the body and the myocardium, the acoustic energy transmitted using an implantable transducer; . . . [and] detecting and providing an indication of the physiological change by chronically detecting the change in the physical property of the body”, as recited in amended claim 19; or
- “a physiological sensor that includes one or more biocompatible bodies, . . . wherein the at least a portion of the one or more bodies is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy to provide an indication of the physiological condition; and an implantable medical device, including one or more acoustic transducers configured to provide acoustic energy to the one or more bodies and to receive responsive acoustic energy, the implantable medical device configured to detect and provide an indication of a change in the physiological condition by using the responsive acoustic energy to detect the change in the physical property of the one or more bodies”, as recited in amended claim 43.

Instead, Slepian '849 apparently relates to “drug particles 14 [that] can be delivered to a desired location within the endomural zone”. (Slepian '849 at page 3, paragraph [0047]; and Fig. 4A.) Slepian '849 states that “[b]iodegradable and/or biocompatible materials may be used to fill, shape, bulk or adhere to voids, cavities, channels or other spaces created by the endomural

therapeutic devices to enhance healing, to provide structural support within the cavity, tubular organ or organ component a to assist or obviate the need for other lumen or cavity support following surgery, and/or for drug delivery.” (Slepian ‘849 at page 5, paragraph [0064].) Slepian ‘849 further states that “[f]or prevention of adhesions or controlled release, the time over which degradation occurs should be correlated with the time required for healing, i.e., generally in excess of two weeks but less than six months.” (Slepian ‘849 at page 6, paragraph [0072].) Applicant respectfully submits that the drug particles of Slepian ‘849 do not appear to function in chronically detecting the change in the physical property, as claimed or substantially claimed in claims 1, 18, 19, and 43. Additionally, Applicant cannot find in Slepian ‘849 an implantable transducer, implantable acoustic transmitter, or implantable medical device, as recited in claims 1, 18, 19, and 43. For at least these reasons, Applicant respectfully submits that Slepian ‘849 does not show each and every recitation of claims 1, 18, 19, and 43.

Additionally, dependent claims 2-9, 11-17, 37, and 38 depend from independent claim 1; dependent claims 40-42 depend from independent claim 18; dependent claims 20-32 and 36 depend from independent claim 19; and dependent claims 44-46 depend from independent claim 43. Accordingly, these claims incorporate the features of one of claims 1, 18, 19, and 43. For reasons analogous to those stated above with respect to claims 1, 18, 19, and 43, claims 2-9, 11-17, 20-32, 36-38, 40-42, and 44-46 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-9, 11-32, 36-38, and 40-46 are allowable over Slepian ‘849 and respectfully requests reconsideration and withdrawal of this rejection.

4. Claims 1-8, 10-12, 16-30, 33, 37, 38, 40, 41, 43, and 46 were rejected under 35 U.S.C. § 102(b) for anticipation by Unger et al. (U.S. Patent No. 6,123,923, hereinafter Unger ‘923). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

It is initially noted that Applicant has canceled claims 10 and 33, thereby rendering the rejection of claims 10 and 33 moot.

Applicant cannot find each and every recitation in claims 1-8, 11-12, 16-30, 37, 38, 40, 41, 43, and 46 in Unger '923. For instance, Applicant cannot find in Unger '923:

- a physiological sensor that includes at least one biocompatible body, . . . at least a portion of the body including a material having at least one physical property that changes in response to a physiological condition of the subject, wherein the change in the at least one physical property is responsive to at least one of a change in pH or a change in an ion concentration, wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer to provide an indication of the physiological condition”, as recited in amended claim 1;
- a plurality of biocompatible spheres, . . . each sphere including at least one physical property that changes in response to a physiological condition of the subject, the at least one physical property being responsive to at least one of a change in pH or a change in an ion concentration; . . . [and] an acoustic receiver, to receive energy from at least one of the spheres and the myocardium, wherein the change in the at least one physical property is chronically detectable using the energy to provide an indication of the physiological condition”, as recited in amended claim 18;
- “introducing a physiological sensor within a myocardium of a subject, the physiological sensor includes at least one body having at least one physical property that changes in response to at least one of a change in pH or a change in an ion concentration; . . . [and] detecting and providing an indication of the physiological change by chronically detecting the change in the physical property of the body”, as recited in amended claim 19; or
- “a physiological sensor that includes one or more biocompatible bodies, . . . at least a portion of the one or more bodies including a material having at least one physical property that changes in response to a physiological condition of the subject, wherein the change in the at least one physical property is responsive to at least one of a change in pH or a change in an ion concentration, and wherein

the at least a portion of the one or more bodies is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy to provide an indication of the physiological condition”, as recited in amended claim 43.

Instead, Unger ‘923 apparently relates to “optoacoustic contrast agents and methods of diagnostic and therapeutic imaging using optoacoustic contrast agents.” (Unger ‘923 at Abstract.) Applicant cannot find any description in Unger ‘923 regarding a biocompatible body including a material having at least one physical property that changes in response at least one of a change in pH or a change in an ion concentration, wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer to provide an indication of the physiological condition, as substantially recited in claim 1 and as similarly claimed in claims 18, 19, and 43. For at least these reasons, Applicant respectfully submits that Unger ‘923 does not show each and every recitation of claims 1, 18, 19, and 43.

Additionally, dependent claims 2-8, 11-12, 16, 17, 37, and 38 depend from independent claim 1; dependent claims 40 and 41 depend from independent claim 18; dependent claims 20-30 depend from independent claim 19; and dependent claim 46 depends from independent claim 43. Accordingly, these claims incorporate the features of one of claims 1, 18, 19, and 43. For reasons analogous to those stated above with respect to claims 1, 18, 19, and 43, claims 2-8, 11-12, 16, 17, 20-30, 37, 38, 40, 41, and 43 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-8, 11-12, 16-30, 37, 38, 40, 41, 43, and 46 are allowable over Unger ‘923 and respectfully requests reconsideration and withdrawal of this rejection.

5. Claims 18, 19, 34, 40, 42, 43, 47, and 48 were rejected under 35 U.S.C. § 102(b) for anticipation by Sutton et al. (U.S. Patent No. 6,348,186, hereinafter Sutton ‘186). In view of the foregoing amendment and the following remarks, Applicant respectfully traverses this rejection.

Applicant cannot find each and every recitation in claims 18, 19, 34, 40, 42, 43, 47, and 48 in Sutton '186. For instance, Applicant cannot find in Sutton '186:

- “a plurality of biocompatible spheres, . . . each sphere including at least one physical property that changes in response to a physiological condition of the subject, the at least one physical property being responsive to at least one of a change in pH or a change in an ion concentration; [and] an implantable acoustic transmitter, to provide energy to the spheres and the myocardium”, as recited in amended claim 18;
- “introducing a physiological sensor within a myocardium of a subject, the physiological sensor includes at least one body having at least one physical property that changes in response to at least one of a change in pH or a change in an ion concentration; [and] transmitting acoustic energy to the body and the myocardium, the acoustic energy transmitted using an implantable transducer”, as recited in amended claim 19; or
- “a physiological sensor that includes one or more biocompatible bodies, . . . at least a portion of the one or more bodies including a material having at least one physical property that changes in response to a physiological condition of the subject, wherein the change in the at least one physical property is responsive to at least one of a change in pH or a change in an ion concentration . . . ; and an implantable medical device, including one or more acoustic transducers configured to provide acoustic energy to the one or more bodies and to receive responsive acoustic energy, the implantable medical device configured to detect and provide an indication of a change in the physiological condition by using the responsive acoustic energy to detect the change in the physical property of the one or more bodies”, as recited in amended claim 43.

Instead, Sutton '186 apparently relates to “the preparation of diagnostic agents comprising hollow microcapsules used to enhance ultrasound imaging.” (Sutton '186 at Abstract.) Sutton '186 states that “the intermediate microspheres prepared in the first step are fixed and rendered less water-soluble so that they persist for longer whilst not being so insoluble and inert that they are not biodegradable.” (Sutton '186 at col. 5, lines 26-29.) Sutton '186



further states that “the wall-forming material can be selected from most hydrophilic, biodegradable physiologically compatible polymers.” (Sutton ‘186 at col. 2, lines 18-20.) Applicant cannot find in Sutton ‘186 a sphere or body having at least one physical property that changes in response to at least one of a change in pH or a change in an ion concentration. Additionally, Applicant cannot find in Sutton ‘186 an implantable acoustic transmitter, implantable transducer, or implantable medical device, as recited in claims 18, 19, and 43, respectively. For at least these reasons, Applicant respectfully submits that Sutton ‘186 does not show each and every recitation of claims 18, 19, and 43.

Additionally, dependent claims 40 and 42 depend from independent claim 18; dependent claim 34 depends from independent claim 19; and dependent claims 47 and 48 depend from independent claim 43. Accordingly, these claims incorporate the features of one of claims 18, 19, and 43. For reasons analogous to those stated above with respect to claims 18, 19, and 43, claims 34, 40, 42, 47, and 48 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 18, 19, 34, 40, 42, 43, 47, and 48 are allowable over Sutton ‘186 and respectfully requests reconsideration and withdrawal of this rejection.

### §103 Rejection of the Claims

1. Claims 1-17, 19-33, 35, 36, 38, and 43-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Altman et al. (U.S. Patent No. 6,296,630) in view of Lew ‘822 and further in view of Siegel as applied above. Applicant respectfully traverses this rejection in view of at least the foregoing amendment and the following remarks.

It is initially noted that Applicant has canceled claims 10 and 33, thereby rendering the rejection of claims 10 and 33 moot.

Applicant respectfully submits that no *prima facie* case of obviousness presently exists because not all of the recitations of claims 1-9, 11-17, 19-32, 35, 36, 38, and 43-46 are taught or suggested by the proposed combination. Applicant cannot find in the proposed combination of

each and every element presently recited in claims 1-9, 11-17, 19-32, 35, 36, 38, and 43-46. For instance, Applicant cannot find in the proposed combination:

- “an implantable transducer; and a physiological sensor that includes at least one biocompatible body, the body sized and shaped to be implanted within a myocardium of a subject, . . . wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer to provide an indication of the physiological condition”, as recited in amended claim 1;
- “introducing a physiological sensor within a myocardium of a subject . . . ; transmitting acoustic energy to the body and the myocardium, the acoustic energy transmitted using an implantable transducer; . . . and detecting and providing an indication of the physiological change by chronically detecting the change in the physical property of the body”, as recited in amended claim 19; or
- “a physiological sensor that includes one or more biocompatible bodies, the one or more bodies sized and shaped to be implanted within a myocardium of a subject, . . . and wherein the at least a portion of the one or more bodies is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy to provide an indication of the physiological condition; and an implantable medical device, including one or more acoustic transducers configured to provide acoustic energy to the one or more bodies and to receive responsive acoustic energy, the implantable medical device configured to detect and provide an indication of a change in the physiological condition by using the responsive acoustic energy to detect the change in the physical property of the one or more bodies”, as recited in amended claim 43.

Instead, Altman et al. apparently relates to “[i]mplantable cardiac drug delivery systems.” (Altman et al. at Abstract.) As stated above, Siegel apparently relates to an “implantable pump for the delivery of insulin”, (Siegel at Abstract) and Lew ‘822 apparently relates to an “implantable chip biosensor for detecting an analyte in vivo in body fluids”, (Lew ‘822 at Abstract). Applicant can find no description in any of the references of the proposed combination related to an implantable transducer or an implantable medical device, as recited in

claims 1, 19, and 43. Additionally, Applicant cannot find in the proposed combination description related to a physiological sensor that includes at least one biocompatible body, wherein the portion of the body is sized and shaped such that the change in the physical property is chronically detectable using acoustic energy supplied by the implantable transducer, as recited in claim 1 and as substantially recited in claims 19 and 43. For at least these reasons, Applicant respectfully submits that the proposed combination does not show each and every recitation of claims 1, 19, and 43.

Additionally, dependent claims 2-9, 11-17, and 38 depend from independent claim 1; dependent claims 20-32, 35, and 36 depend from independent claim 19; and dependent claims 44-46 depend from independent claim 43. Accordingly, these claims incorporate the features of one of claims 1, 19, and 43. For reasons analogous to those stated above with respect to claims 1, 19, and 43, claims 2-9, 11-17, 20-32, 35, 36, 38, and 44-46 are accordingly believed to be patentable. For brevity, Applicant defers (but reserves the right to present) further remarks, such as concerning any dependent claims, which are believed separately patentable.

For at least these reasons, Applicant submits that claims 1-9, 11-17, 19-32, 35, 36, 38, and 43-46 are allowable over the proposed combination and respectfully requests reconsideration and withdrawal of this rejection.

2. Claims 34, 47, and 48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lew '822, Slepian '849, or Unger '923, each in view of Sutton '186. In view of at least the foregoing amendment, Applicant respectfully traverses this rejection.

Applicant respectfully traverses this rejection on the grounds that no *prima facie* case of obviousness presently exists with respect to claims 34, 47, and 48 because not all of the claim recitations are taught or suggested by the proposed combinations. Claim 34 depends from independent claim 19; and claims 47 and 48 depend from independent claim 43. Accordingly, claims 34, 47, and 48 each incorporate the features of one of claims 19 and 43. Therefore, Applicant submits that claims 34, 47, and 48 are patentable over the proposed combinations based upon at least their dependence from one of claims 34, 47, and 48, which are believed to be in condition for allowance for the reasons stated above. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34, 47, and 48.

*Allowable Subject Matter*

Claim 39 was objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 39 depends from claim 1, which, for at least the reasons stated above, is believed to be in condition for allowance. Therefore, Applicant respectfully submits that the claim 39 is allowable in its present form, and Applicant respectfully requests allowance of the claim 39.

**RESERVATION OF RIGHTS**

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any canceled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

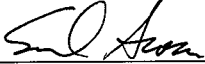
**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

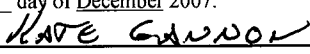
If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

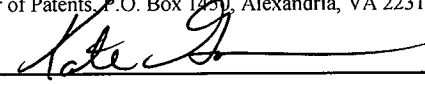
Respectfully submitted,

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Date December 17, 2007 By   
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 17 day of December 2007.

  
Name

  
Signature